Remarks

The Office Action mailed March 9, 2007, has been received and reviewed. Claims 20 and 21 having been amended and claims 1-11, 14-19, 22-26, 29-35, 37-44, 46, 48, 51-56, and 60-75 having been canceled, without prejudice, the pending claims are claims 12, 13, 20, 21, 27, 28, 36, 45, 47, 49, 50, 57-59, and 76-83. Claims 21, 57-59, 76, and 77 being withdrawn from consideration as drawn to non-elected inventions, claims 12, 13, 20, 27, 28, 36, 45, 47, 49, 50, and 78-83 are currently under examination. Reconsideration and withdrawal of the rejections are respectfully requested.

As amended, Applicants submit that claim 21, drawn to an isolated polypeptide, properly belongs to the group elected in response to the Restriction Requirement mailed October 10, 2006 (an isolated polypeptide; SEQ ID NO:6). The rejoinder and examination of claim 21 is requested.

Clarification of the status of claim 36 is requested. Pending claim 36 is not included in any of the rejections of record in the Office Action mailed March 9, 2007 (see pages 2 and 4 of the Office Action mailed March 9, 2007).

The 35 U.S.C. §101 Rejection

The Examiner rejected claims 12, 13, 20, 27, 28, 45, 47, 49, 50, and 78-83 under 35 U.S.C. §101, asserting that the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility. This rejection is respectfully traversed. Applicants submit that the polypeptide of claims 12, 13, 20, 27, 28, 36, 45, 47, 49, 50, and 78-83 has substantial and specific utility.

Claims 12, 13, 78, and 79 are drawn to polypeptides "encoded by a polynucleotide that hybridizes to SEQ ID NO:5 under stringent hybridization conditions, wherein the polypeptide is capable of Na^+-dependent transmembrane transport of citrate;" claims 20, 27, 28, 36, 45, 47, 49, 50, and 80-83 are drawn to polypeptides "comprising an amino acid sequence having at least 75% identity to SEQ ID NO:6, wherein the polypeptide is capable of Na^+-dependent transmembrane transport of citrate." Exemplifying the claimed invention is the human Na^+-

coupled citrate transporter ("NaCT") having SEQ ID NO:6. "When functionally expressed in mammalian cells, human NaCT mediates the Na^+-coupled transport of citrate. . . . The activation of citrate transport by Na+ is sigmoidal, suggesting involvement of multiple Na^+ ions in the activation process. The transport process is electrogenic. This represents the first plasma membrane transporter in humans that mediates the preferential entry of citrate into cells. Citrate occupies a pivotal position in many important biochemical pathways" (page 72, lines 10-19 of the specification).

Applicants submit that the specification demonstrates the substantial and specific utility of the claimed polypeptides. For example, Applicants direct the Examiner to Example 7 (pages 119-129 of the specification). Example 7 demonstrates that the human NaCT polypeptide, when functionally expressed *in vitro* in a mammalian host cell line, serves as an assay to distinguish between medications that impact citrate metabolism (with resultant negative side effects such as weight gain, obesity, hypercholesterolemia, hyperlipidemia, hyperglycemia, and insulin-resistant diabetes) and medications that do not impact citrate metabolism (and, thus, do not demonstrate such negative side effects). Lithium, valproate and carbamazepine are all mood stabilizing drugs used for the treatment of bipolar disease (page 128, lines 4-6 of the specification). The association of lithium therapy with a significant increase in body weight has been known for some time, a side effect not observed with valproate or carbamazepine. As shown in Example 7, the human NaCT polypeptide, when functionally expressed *in vitro* in a mammalian host cell line, distinguishes between lithium (which activates the human NaCT and stimulates the uptake of citrate into the cell) and valproate or carbamazepine (which do not affect the function of human NaCT) (see, for example, page 120, page 124, lines 6-18 and page 128, lines 1-17 of the specification). Thus, the claimed polypeptides have a real world, substantial and specific utility, for use in assays to distinguish between medications that impact citrate metabolism (with concomitant, negative side effects such as weight gain, obesity, hypercholesterolemia, hyperlipidemia, hyperglycemia, and insulin-resistant diabetes) and medications that do not impact citrate metabolism (and, thus, do not demonstrate such negative side effects).

As a further demonstration of the real world utility of the present invention, Applicants reference the existence of the License Agreement in place between Medical College of Georgia Research Institute, Inc. ("MCGRI," the assignee of all right, title, and interest in the present application) and Elixir Pharmaceuticals, Inc. A redacted copy of this License Agreement is included herewith as Exhibit A. With this License Agreement, MCGRI grants rights to Elixir Pharmaceuticals to develop and commercialize the claimed invention. For example, MCGRI grants rights to use the claimed polypeptides "to identify hit molecules . . . that block transport of citrate via the . . . (NaCT) cell surface receptor. These hits form the basis of a drug discovery program intended to treat metabolic disorders" (see page 23 of the License Agreement). Applicants submit that the polypeptides of the claimed invention have a real world utility.

The Examiner asserted that "[t]he claimed polypeptides do not [have] substantial utility because the skilled artisan would need to prepare, isolate, and analyze the transporter polypeptide in order to determine its function and use. Therefore, the invention is not available in a readily available form. Instead, further experimentation would have to determine the function of the transporter" (page 3, Office Action mailed March 9, 2007). Applicants do not understand the basis of this assertion and respectfully submit that the Examiner's assertions is incorrect. Applicants submit that the specification amply details the function and use of the claimed NaCT polypeptides (see, for example, page 5, line 28 to page 6, line 2; page 7, lines 16-22; page 8, lines 17-30; page 20, lines 26-33; page 21, lines 5-21; page 38, line 22 to page 40, line 7; Example 3 (pages 72-82); Example 7 (pages 119-129); and Example 8 (page 130) of the specification).

Citing Brenner v. Manson (383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966)) the Examiner asserted that "'Congress intended that no patents be granted on an chemical compound whose sole 'utility' consists of its potential role as an object of use-testing . . . a patent is not a hunting license'" (page 4, Office Action mailed March 9, 2007). Again, Applicants do not understand the relevance of this assertion to the presently claimed polypeptides. Again, Applicants submit that the present specification amply details the function and use of the presently claimed invention; no hunting is required on the part of the skilled artisan.

As discussed above, the claimed polypeptides have substantial and specific utility. Reconsideration and withdrawal of this rejection of claims 12, 13, 20, 27, 28, 45, 47, 49, 50, and 78-83 under 35 U.S.C. §101 is requested.

The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 12, 13, 20, 27, 28, 45, 47, 49, 50, and 78-83 under 35 U.S.C. §112, first paragraph, asserting that "[s]pecifically since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention" (page 4, Office Action mailed March 9, 2007). As presented above, Applicants submit that claims 12, 13, 20, 27, 28, 45, 47, 49, 50, and 78-83 have a substantial and specific utility. Thus, this rejection of the claims under 35 U.S.C. §112, first paragraph, is moot. Reconsideration and withdrawal of the rejection of claims 12, 13, 20, 27, 28, 45, 47, 49, 50, and 78-83 under 35 U.S.C. §112, first paragraph, is respectfully requested.

Amendment and Response
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Summary

It is respectfully submitted that the pending claims 12, 13, 20, 21, 27, 28, 36, 45, 47, 49, 50, 57-59, and 76-83 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted
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CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to **Mail Stop Amendment**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450,
on this 6 day of August, 2007, at 8:40 A.M. (Central Time).

By: Sandy Trueheart
Name: Sandy Trueheart